

NCIC HPV Sent by: Mary-Beth Weaver

05/23/2003 09:54 AM

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CC:

Subject: Environmental Defense comments on 2,4,6-Trimethylphenol (CAS# 527-60-6)



Richard Denison@environmentaldefense.org on 05/22/2003 10:36:23 AM

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(Submitted via Internet 5/22/03 to oppt.ncic@epa.gov, hpv.chemrtk@epa.gov, boswell.karen@epa.gov, chem.rtk@epa.gov, MTC@mchsi.com, and Ronald.Joiner@GEP.GE.COM)

Environmental Defense appreciates this opportunity to submit comments on the robust summary/test plan for 2,4,6-Trimethylphenol (CAS# 527-60-6).

General Electric Company, in response to EPA's High Production Volume Challenge Program, has submitted a Robust Summary/Test Plan for 2,4,6-trimethylphenol (TMP). This Test Plan is somewhat unique in that it consists of a single page that describes the chemical structure, synonyms, actual production volume and primary use of TMP. It is also stated that approximately 3 million pounds of TMP are sold to two customers annually. However, no mention is made of methods of transport, possible sources of environmental release or environmental or human exposure. The Test Plan does contain a matrix of SIDS elements that have been addressed by available data, or computer modeling and judges the quality of these data. The General Electric Company is to be complimented on the fact that they plan to repeat some of the studies of Physical and Chemical Data in order to determine these parameters more accurately. They also propose to conduct studies of Repeated Dose Toxicity, Reproductive Toxicity and Developmental Toxicity/Teratogenicity to provide data that are currently not available, proposal with which we concur.

The Robust Summary is also somewhat unique in that it describes, in considerable detail, one study to address each requested SIDS element. These descriptions are frequently quite long and overly detailed, but they are thorough. These data indicate that TMP is quite stable in the environment, and thus has significant potential to accumulate in the environment if released. The data also indicate it is moderately toxic to fish, aquatic invertebrates and plants. These findings emphasize the importance of information regarding potential sources of environmental release that are currently missing from the Test Plan.

Most of the studies described in the Robust Summary are recent and conducted under GLP. However, the study of acute toxicity to mammals was not conducted under GLP and would not be considered acceptable by today's standards. These data do seem sufficient to us to indicate TMP has relatively low oral toxicity to rats and low dermal toxicity to rabbits. Therefore, since additional animal studies are proposed, we would not recommend any further studies of acute toxicity.

The Robust Summary consists primarily of descriptions of how studies are

conducted, how the results are analyzed, etc. Only one study is described to address each requested SIDS element. However, a brief search of TOXLINE indicates that several dozen papers have been published on this chemical describing different aspects of its toxicity and presence in the environment. Whereas most of these papers do not address the SIDS elements requested by the EPA under the HPV Challenge Program, a number of them do. Further, there are a number of papers describing the release, presence and/or persistence of TMP in the environment. Thus, both the Test Plan and the Robust Summary submitted for TMP can and should be a good deal more informative than they are at present.

Thank you for this opportunity to comment.

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